IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	C.A. No. 18-00341-VAC-MPT

DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.'S ANSWER AND ADDITIONAL DEFENSES TO THE COMPLAINT

Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL"), by and through their undersigned attorneys, hereby answer the Complaint of BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A. (collectively, "Bial") and Sunovion Pharmaceuticals Inc. ("Sunovion") (collectively, "Plaintiffs") as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), DRL denies all allegations in Plaintiffs' Complaint except those specifically admitted below.

THE PARTIES

1. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 1 of the Complaint, and therefore denies those allegations.

2. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 2 of the Complaint, and therefore denies those allegations.

3. DRL admits that APTIOM® is a pharmaceutical product approved for marketing in the United States and indicated for "the treatment of partial-onset seizures in patients 4 years of age and older." DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 3 of the Complaint, and therefore denies those allegations.

4. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 4 of the Complaint, and therefore denies those allegations.

5. DRL admits that Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh 500034, India. DRL denies the remaining allegations of Paragraph 5 of the Complaint.

6. DRL admits that Dr. Reddy's Laboratories, Ltd. develops, manufactures and markets pharmaceutical products. DRL denies the remaining allegations in Paragraph 6 of the Complaint.

7. Admitted.

8. Admitted.

9. DRL admits that Dr. Reddy's Laboratories, Inc. develops, manufactures and markets pharmaceutical products. DRL denies the remaining allegations in Paragraph 9 of the Complaint.

10. DRL admits that Dr. Reddy's Laboratories, Inc. filed Abbreviated New Drug Application ("ANDA") No. 211238 with the United States Food and Drug Administration ("FDA") on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 10 of the Complaint.

11. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 11 of the Complaint.

NATURE OF THE ACTION

12. DRL admits that the Complaint purports to be a civil action for patent infringement of U.S. Patent Nos. 8,372,431 ("the '431 patent"), 9,206,135 ("the '135 patent"), 9,566,244 ("the '244 patent"), 9,643,929 ("the '929 patent"), 9,750,747 ("the '747 patent") and 9,763,954 ("the '954 patent") (collectively, "patents-in-suit") arising under the patent laws of the United States. DRL further admits that the Complaint purports to be an action relating to DRL's filing of ANDA No. 211238 with the FDA pursuant to Section 505(j) of the United States Food, Drug, and Cosmetic Act. DRL further admits that it seeks to obtain approval of its eslicarbazepine acetate tablets 200, 400, 600, and 800 mg described in ANDA No. 211238 ("DRL's ANDA Product") prior to the expiration of the patents-in-suit. DRL denies the remaining allegations in Paragraph 12 of the Complaint.

JURISDICTION AND VENUE

13. DRL incorporates by reference each of its answers to Paragraphs 1-12 above as if fully set forth herein.

14. For purposes of this action only, DRL admits personal jurisdiction and venue in this Court. DRL denies the remaining allegations in Paragraph 14 of the Complaint.

15. For purposes of this action only, DRL admits venue and personal jurisdiction in this Court. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 15 of the Complaint, and therefore denies those allegations.

16. DRL admits that the Complaint states that this is a civil action for patent infringement and declaratory judgement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., including 35 U.S.C. § 271, and the Declaratory Judgement Act, 28 U.S.C. §§ 2201 and 2202. DRL denies the remaining allegations in Paragraph 16 of the Complaint.

17. Paragraph 17 of the Complaint states a conclusion of law to which no response is required.

18. For purposes of this action only, DRL admits venue in this Court. DRL denies the remaining allegations in Paragraph 18 of the Complaint.

19. For purposes of this action only, DRL admits personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 19 of the Complaint.

20. For purposes of this action only, DRL admits personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 20 of the Complaint.

21. For purposes of this action only, DRL admits personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 21 of the Complaint.

22. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 22 of the Complaint.

23. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 23 of the Complaint.

24. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 24 of the Complaint.

25. For purposes of this action only, DRL admits personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 25 of the Complaint.

26. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 26 of the Complaint.

27. DRL admits that the alleged website speaks for itself. For purposes of this action only, DRL admits personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 27 of the Complaint.

28. For purposes of this action only, DRL admits personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 28 of the Complaint.

29. For purposes of this action only, DRL admits personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 29 of the Complaint.

FACTUAL BACKGROUND

The NDA

30. DRL admits that the "Approved Drug Products with Therapeutic Equivalence Evaluations" ("*Orange Book*"), published by the FDA at https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=022416, lists "Sunovion Pharmaceuticals Inc" as the holder of New Drug Application ("NDA") No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets, in 200, 400, 600 and 800 mg dosage strengths. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 30 of the Complaint, and therefore denies those allegations.

31. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 31 of the Complaint, and therefore denies those allegations.

32. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 32 of the Complaint, and therefore denies those allegations.

33. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 33 of the Complaint, and therefore denies those allegations.

34. DRL admits that the presently approved Prescribing Information for APTIOM® is a document that speaks for itself. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 34 of the Complaint, and therefore denies those allegations.

The Patents-in-Suit

35. DRL admits that the '431 patent, on its face, is entitled "Pharmaceutical composition comprising licarbazepine acetate" and states the date of issue as February 12, 2013. DRL further admits that Exhibit A purports to be a true and correct copy of the '431 patent. DRL denies the remaining allegations in Paragraph 35 of the Complaint.

36. Paragraph 36 of the Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '431 patent, on its face, lists "BIAL – Portela & C.A., S.A., S. Mamede do Coronado (PT)" as the assignee, and that according to the Orange Book published by the FDA, the '431 patent will expire on April 17, 2030. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 36 of the Complaint, and therefore denies those allegations.

37. On information and belief DRL admits that the '431 patent is listed in the Orange Book published by the FDA for NDA No. 022416 for Eslicarbazepine Acetate (APTIOM) Tablets. DRL denies the remaining allegations of Paragraph 37 of the Complaint.

38. DRL admits that the ‘135 patent, on its face, is entitled “Asymmetric catalytic reduction of oxcarbezepine” and states the date of issue as December 8, 2015. DRL further admits that Exhibit B purports to be a true and correct copy of the ‘135 patent. DRL denies the remaining allegations in Paragraph 38 of the Complaint.

39. Paragraph 39 of the Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the ‘135 patent, on its face, lists “BIAL – Portela & CA, S.A., S. Mamede do Coronado (PT)” as the assignee, and that according to the Orange Book published by the FDA, the ‘135 patent will expire on April 21, 2026. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 39 of the Complaint, and therefore denies those allegations.

40. On information and belief DRL admits that the ‘135 patent is listed in the Orange Book published by the FDA for NDA No. 022416 for Eslicarbazepine Acetate (APTIOM) Tablets. DRL denies the remaining allegations of Paragraph 40 of the Complaint.

41. DRL admits that the ‘244 patent, on its face, is entitled “Pharmaceutical composition comprising licrbazepine acetate” and states the date of issue as February 14, 2017. DRL further admits that Exhibit C purports to be a true and correct copy of the ‘244 patent. DRL denies the remaining allegations in Paragraph 41 of the Complaint.

42. Paragraph 42 of the Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the ‘244 patent, on its face, lists “BIAL – Portela & CA, S.A., S. Mamede do Coronado (PT)” as the assignee, and that according to the Orange Book published by the FDA, the ‘244 patent will expire on October 23, 2028. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 42 of the Complaint, and therefore denies those allegations.

43. On information and belief DRL admits that the '244 patent is listed in the Orange Book published by the FDA for NDA No. 022416 for Eslicarbazepine Acetate (APTIOM) Tablets. DRL denies the remaining allegations of Paragraph 43 of the Complaint.

44. DRL admits that the '929 patent, on its face, is entitled "Asymmetric catalytic reduction of oxcarbezepine" and states the date of issue as May 9, 2017. DRL further admits that Exhibit D purports to be a true and correct copy of the '929 patent. DRL denies the remaining allegations in Paragraph 44 of the Complaint.

45. Paragraph 45 of the Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '929 patent, on its face, lists "BIAL – Portela & CA, S.A., S. Mamede do Coronado (PT)" as the assignee, and that according to the Orange Book published by the FDA, the '929 patent will expire on April 21, 2026. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 45 of the Complaint, and therefore denies those allegations.

46. On information and belief DRL admits that the '929 patent is listed in the Orange Book published by the FDA for NDA No. 022416 for Eslicarbazepine Acetate (APTIOM) Tablets. DRL denies the remaining allegations of Paragraph 46 of the Complaint.

47. DRL admits that the '747 patent, on its face, is entitled "Treatments involving eslicarbazepine acetate or eslicarbazepine" and states the date of issue as September 5, 2017. DRL further admits that Exhibit E purports to be a true and correct copy of the '747 patent. DRL denies the remaining allegations in Paragraph 47 of the Complaint.

48. Paragraph 48 of the Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '747 patent, on its face, lists "BIAL – Portela & CA, S.A., Sao Mamede do Coronado (PT)" as the assignee, and that

according to the Orange Book published by the FDA, the '747 patent will expire on August 24, 2032. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 48 of the Complaint, and therefore denies those allegations.

49. On information and belief DRL admits that the '747 patent is listed in the Orange Book published by the FDA for NDA No. 022416 for Eslicarbazepine Acetate (APTIOM) Tablets. DRL denies the remaining allegations of Paragraph 49 of the Complaint.

50. DRL admits that the '954 patent, on its face, is entitled "Therapeutical uses of eslicarbazepine" and states the date of issue as September 19, 2017. DRL further admits that Exhibit F purports to be a true and correct copy of the '954 patent. DRL denies the remaining allegations in Paragraph 50 of the Complaint.

51. Paragraph 51 of the Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '954 patent, on its face, lists "BIAL – Portela & CA, S.A., S. Mamede do Coronado (PT)" as the assignee, and that according to the Orange Book published by the FDA, the '954 patent will expire on September 13, 2028. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 51 of the Complaint, and therefore denies those allegations.

52. On information and belief DRL admits that the '954 patent is listed in the Orange Book published by the FDA for NDA No. 022416 for Eslicarbazepine Acetate (APTIOM) Tablets. DRL denies the remaining allegations of Paragraph 52 of the Complaint.

The ANDA

53. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 53 of the Complaint.

54. DRL admits that DRL's ANDA contains a Paragraph IV Patent Certification in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 CFR § 314.94(a)(12)(i)(A)(4) that the patents-in-suit are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of DRL's ANDA Product. DRL denies the remaining allegations in Paragraph 54 of the Complaint.

55. DRL admits that it sent copies of its "Notice of Paragraph IV Certification" ("DRL's Notice Letter") dated January 17, 2018 with respect to DRL's ANDA Product and the patents-in-suit to Sunovion and Bial and that DRL's Notice Letter is a document that speaks for itself. DRL further admits that DRL's Notice Letter notified Plaintiffs that DRL had submitted ANDA No. 211238 to the FDA for approval of the matters therein prior to the expiration of the patents-in-suit. On information and belief DRL further admits that DRL's Notice Letter was delivered to Sunovion and Bial on or about January 18, 2018 and January 22, 2018, respectively. DRL denies the remaining allegations in Paragraph 55 of the Complaint.

56. DRL admits that the Complaint was filed on March 2, 2018 and that said date is within 45 days of January 18, 2018. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 56 of the Complaint, and therefore denies those allegations.

COUNT I

(ALLEGED INFRINGEMENT OF THE '431 PATENT UNDER 35 U.S.C. § 271(e)(2))

57. DRL incorporates by reference each of its answers to Paragraphs 1-56 above as if fully set forth herein.

58. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein prior to the

expiration of the patents-in-suit, including the '431 patent. DRL denies the remaining allegations in Paragraph 58 of the Complaint.

59. DRL admits that DRL's ANDA contains a Paragraph IV Patent Certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act and 21 CFR § 314.94(a)(12)(i)(A)(4) that the patents-in-suit, including the '431 patent, are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of DRL's ANDA Product. DRL denies the remaining allegations in Paragraph 59 of the Complaint.

60. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein and that said ANDA is a document that speaks for itself. DRL denies the remaining allegations in Paragraph 60 of the Complaint.

61. DRL admits that DRL's submission of ANDA No. 211238 to the FDA accompanied by a Paragraph IV certification with respect to the '431 patent constituted a technical act of infringement under 35 U.S.C § 271(e)(2) only for the purpose conferring subject matter jurisdiction with respect to that patent. DRL denies the remaining allegations of Paragraph 61.

62. DRL denies the allegations in Paragraph 62 of the Complaint.

63. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 63 of the Complaint.

64. DRL denies the allegations in Paragraph 64 of the Complaint.

65. DRL denies the allegations in Paragraph 65 of the Complaint.

66. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 66 of the Complaint.

67. DRL denies the allegations in Paragraph 67 of the Complaint.

COUNT II

(ALLEGED INFRINGEMENT OF THE '135 PATENT UNDER 35 U.S.C. § 271(e)(2))

68. DRL incorporates by reference each of its answers to Paragraphs 1-67 above as if fully set forth herein.

69. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein prior to the expiration of the patents-in-suit, including the '135 patent. DRL denies the remaining allegations in Paragraph 69 of the Complaint.

70. DRL admits that DRL's ANDA contains a Paragraph IV Patent Certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act and 21 CFR § 314.94(a)(12)(i)(A)(4) that the patents-in-suit, including the '135 patent, are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of DRL's ANDA Product. DRL denies the remaining allegations in Paragraph 70 of the Complaint.

71. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein and that said ANDA is a document that speaks for itself. DRL denies the remaining allegations in Paragraph 71 of the Complaint.

72. DRL admits that DRL's submission of ANDA No. 211238 to the FDA accompanied by a Paragraph IV certification with respect to the '135 patent constituted a

technical act of infringement under 35 U.S.C § 271(e)(2) only for the purpose conferring subject matter jurisdiction with respect to that patent. DRL denies the remaining allegations of Paragraph 72.

73. DRL denies the allegations in Paragraph 73 of the Complaint.

74. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 74 of the Complaint.

75. DRL admits that DRL was aware of the '135 patent when it submitted ANDA No. 211238 to the FDA. DRL denies the remaining allegations in Paragraph 75 of the Complaint.

76. DRL denies the allegations in Paragraph 76 of the Complaint.

77. DRL admits that DRL was aware of the '135 patent when it submitted ANDA No. 211238 to the FDA. DRL denies the remaining allegations in Paragraph 77 of the Complaint.

78. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 78 of the Complaint.

79. DRL denies the allegations in Paragraph 79 of the Complaint.

80. DRL denies the allegations in Paragraph 80 of the Complaint.

81. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 81 of the Complaint.

82. DRL denies the allegations in Paragraph 82 of the Complaint.

COUNT III

(INFRINGEMENT OF THE '244 PATENT UNDER 35 U.S.C. § 271(e)(2))

83. DRL incorporates by reference each of its answers to Paragraphs 1-82 above as if fully set forth herein.

84. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein prior to the expiration of the patents-in-suit, including the '244 patent. DRL denies the remaining allegations in Paragraph 84 of the Complaint.

85. DRL admits that DRL's ANDA contains a Paragraph IV Patent Certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act and 21 CFR § 314.94(a)(12)(i)(A)(4) that the patents-in-suit, including the '244 patent, are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of DRL's ANDA Product. DRL denies the remaining allegations in Paragraph 85 of the Complaint.

86. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein and that said ANDA is a document that speaks for itself. DRL denies the remaining allegations in Paragraph 86 of the Complaint.

87. DRL admits that DRL's submission of ANDA No. 211238 to the FDA accompanied by a Paragraph IV certification with respect to the '244 patent constituted a technical act of infringement under 35 U.S.C § 271(e)(2) only for the purpose conferring subject matter jurisdiction with respect to that patent. DRL denies the remaining allegations of Paragraph 87.

88. DRL denies the allegations in Paragraph 88 of the Complaint.

89. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 89 of the Complaint.

90. DRL denies the allegations in Paragraph 90 of the Complaint.

91. DRL denies the allegations in Paragraph 91 of the Complaint.

92. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 92 of the Complaint.

93. DRL denies the allegations in Paragraph 93 of the Complaint.

COUNT IV

(ALLEGED INFRINGEMENT OF THE '929 PATENT UNDER 35 U.S.C. § 271(e)(2))

94. DRL incorporates by reference each of its answers to Paragraphs 1-93 above as if fully set forth herein.

95. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein prior to the expiration of the patents-in-suit, including the '929 patent. DRL denies the remaining allegations in Paragraph 95 of the Complaint.

96. DRL admits that DRL's ANDA contains a Paragraph IV Patent Certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act and 21 CFR § 314.94(a)(12)(i)(A)(4) that the patents-in-suit, including the '929 patent, are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of DRL's ANDA Product. DRL denies the remaining allegations in Paragraph 96 of the Complaint.

97. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein and that said ANDA is a document that speaks for itself. DRL denies the remaining allegations in Paragraph 97 of the Complaint.

98. DRL admits that DRL's submission of ANDA No. 211238 to the FDA accompanied by a Paragraph IV certification with respect to the '929 patent constituted a technical act of infringement under 35 U.S.C § 271(e)(2) only for the purpose conferring subject matter jurisdiction with respect to that patent. DRL denies the remaining allegations of Paragraph 98.

99. DRL denies the allegations in Paragraph 99 of the Complaint.

100. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 100 of the Complaint.

101. DRL denies the allegations in Paragraph 101 of the Complaint.

102. DRL denies the allegations in Paragraph 102 of the Complaint.

103. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 103 of the Complaint.

104. DRL denies the allegations in Paragraph 104 of the Complaint.

COUNT V

(ALLEGED INFRINGEMENT OF THE '747 PATENT UNDER 35 U.S.C. § 271(e)(2))

105. DRL incorporates by reference each of its answers to Paragraphs 1-104 above as if fully set forth herein.

106. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein prior to the expiration of the patents-in-suit, including the '747 patent. DRL denies the remaining allegations in Paragraph 106 of the Complaint.

107. DRL admits that DRL's ANDA contains a Paragraph IV Patent Certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act and 21 CFR § 314.94(a)(12)(i)(A)(4) that the patents-in-suit, including the '747 patent, are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of DRL's ANDA Product. DRL denies the remaining allegations in Paragraph 107 of the Complaint.

108. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein and that said ANDA is a document that speaks for itself. DRL denies the remaining allegations in Paragraph 108 of the Complaint.

109. DRL admits that DRL's submission of ANDA No. 211238 to the FDA accompanied by a Paragraph IV certification with respect to the '747 patent constituted a technical act of infringement under 35 U.S.C § 271(e)(2) only for the purpose conferring subject matter jurisdiction with respect to that patent. DRL denies the remaining allegations of Paragraph 109.

110. DRL denies the allegations in Paragraph 110 of the Complaint.

111. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 111 of the Complaint.

112. DRL admits that that DRL was aware of the '747 patent when it submitted ANDA No. 211238 to the FDA. DRL denies the remaining allegations in Paragraph 112 of the Complaint.

113. DRL denies the allegations in Paragraph 113 of the Complaint.

114. DRL admits that DRL was aware of the '747 patent when it submitted ANDA No. 211238 to the FDA. DRL denies the remaining allegations in Paragraph 114 of the Complaint.

115. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 115 of the Complaint.

116. DRL denies the allegations in Paragraph 116 of the Complaint.

117. DRL denies the allegations in Paragraph 117 of the Complaint.

118. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 118 of the Complaint.

119. DRL denies the allegations in Paragraph 119 of the Complaint.

COUNT VI

(ALLEGED INFRINGEMENT OF THE '954 PATENT UNDER 35 U.S.C. § 271(e)(2))

120. DRL incorporates by reference each of its answers to Paragraphs 1-119 above as if fully set forth herein.

121. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein prior to the expiration of the patents-in-suit, including the '954 patent. DRL denies the remaining allegations in Paragraph 121 of the Complaint.

122. DRL admits that DRL's ANDA contains a Paragraph IV Patent Certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act and 21 CFR § 314.94(a)(12)(i)(A)(4) that the patents-in-suit, including the '954 patent, are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of DRL's ANDA Product. DRL denies the remaining allegations in Paragraph 122 of the Complaint.

123. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein and that said ANDA is a document that speaks for itself. DRL denies the remaining allegations in Paragraph 123 of the Complaint.

124. DRL admits that DRL's submission of ANDA No. 211238 to the FDA accompanied by a Paragraph IV certification with respect to the '954 patent constituted a technical act of infringement under 35 U.S.C § 271(e)(2) only for the purpose conferring subject matter jurisdiction with respect to that patent. DRL denies the remaining allegations of Paragraph 124.

125. DRL denies the allegations in Paragraph 125 of the Complaint.

126. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 126 of the Complaint.

127. DRL admits that that DRL was aware of the '954 patent when it submitted ANDA No. 211238 to the FDA. DRL denies the remaining allegations in Paragraph 127 of the Complaint.

128. DRL denies the allegations in Paragraph 128 of the Complaint.

129. DRL admits that that DRL was aware of the '954 patent when it submitted ANDA No. 211238 to the FDA. DRL denies the remaining allegations in Paragraph 129 of the Complaint.

130. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 130 of the Complaint.

131. DRL denies the allegations in Paragraph 131 of the Complaint.

132. DRL denies the allegations in Paragraph 132 of the Complaint.

133. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 133 of the Complaint.

134. DRL denies the allegations in Paragraph 134 of the Complaint.

RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

DRL denies that Plaintiffs are entitled to the relief they seek in Paragraphs (A) – (H) or any relief at all for the allegations made in the Complaint.

ADDITIONAL DEFENSES

On information and belief, DRL alleges and asserts the following Additional Defenses to Plaintiffs' Complaint. DRL asserts these Additional Defenses without conceding that it bears the burden of proof on them.

FIRST DEFENSE
(Failure to State a Claim Upon Which Relief Can be Granted)

Each of Plaintiffs' allegations of infringement of each of the patents-in-suit fails to state a claim upon which relief can be granted.

SECOND DEFENSE

(Non-infringement of the ‘431, ‘135, ‘244, ‘929, ‘747 and ‘954 patents)

The manufacture, use, sale, offer for sale and/or importation into the United States of DRL’s ANDA Product does not and will not directly or indirectly infringe, induce infringement of, or contribute to the infringement of any valid and enforceable claim of the ‘431, ‘135, ‘244, ‘929, ‘747 and ‘954 patents, either literally or under the doctrine of equivalents.

THIRD DEFENSE
(Invalidity of the ‘431, ‘135, ‘244, ‘929, ‘747 and ‘954 patents)

The claims of the ‘431, ‘135, ‘244, ‘929, ‘747 and ‘954 patents are invalid for failing to satisfy one or more of the requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or non-statutory double patenting.

RESERVATION OF ADDITIONAL DEFENSES

DRL reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional defenses are appropriate, including, but not limited to, defenses of unenforceability, as well as any defense(s) raised by a defendant in a consolidated action.

REQUEST FOR RELIEF

WHEREFORE, DRL respectfully requests the following relief:

A. Dismissing the Complaint with prejudice and denying each request for relief made by Plaintiffs;

B. Adjudging that no valid and enforceable claim of the ‘431, ‘135, ‘244, ‘929, ‘747 and ‘954 patents is infringed, directly or indirectly, by the manufacture, use, sale, offer for sale in the United States and/or importation into the United States of DRL’s eslicarbazepine acetate tablets, 200, 400, 600, and 800 mg, that are the subject of ANDA No. 211238, either literally or under the doctrine of equivalents;

C. Adjudging that the ‘431, ‘135, ‘244, ‘929, ‘747 and ‘954 patents are invalid;

D. Adjudging that this is an exceptional case under 35 U.S.C. § 285 and awarding DRL its attorneys' fees, costs, and expenses in this action; and

E. Awarding DRL its costs and such other and further relief as the Court deems just and proper.

Dated: April 20, 2018

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